REMARKS

Claims 21-33 are pending. Claims 28-33 are withdrawn. Claim 26 is cancelled, without prejudice. Claim 34 is new. Support for new Claim 34 can be found in previously filed claim 23. The Specification is amended to correct typographical errors. Claims 21-25 are amended. Support for these amendments can be found, e.g., throughout the Specification.

Applicant believes that no new matter is added by way of amendment.

I. Objections to the Specification.

The Examiner objected to the title and to typographical errors in the specification. Applicant has made the necessary corrections in the above amendments.

In view of the foregoing amendment, Applicant respectfully requests withdrawal of the objections to the Specification.

II. Rejection of Claims 21-24 under 35 U.S.C. 101.

The Examiner rejected Claims 21-24 under 35 U.S.C. 101 as being directed to non-statutory subject matter. Applicant amended claim 21 to recite "isolated or purified", and is now directed to statutory subject matter, as are Claims 22-24, which depend from Claim 21.

In view of the foregoing amendment, Applicant respectfully requests withdrawal of the rejection of Claims 21-24 under 35 U.S.C. 101.

III. Rejections of Claims 21-27 under 35 U.S.C. §101 and §112, First Paragraph.

The Examiner rejected Claims 21-27 under 35 U.S.C. §101 and §112, first paragraph, on the basis that the claimed invention is not supported by a credible, specific, or substantial asserted utility. Claim 26 is canceled and the rejection is moot as to this claim. The Examiner alleges Applicant's assertion that the polypeptides of the present invention have biological activities similar to known IL-1 family members cannot be accepted in the absence of supporting evidence. Applicant is only required to provide evidence if, when considered as a whole, leads the skilled artisan to

conclude that the asserted utility is more likely than not true (see, e.g., M.P.E.P section 2107.03).

The specification states that the molecule of the present invention, IL-1z, has ". . . substantial likelihood of synergy with other IL-1 or IL-12 antagonists or agonists." (see, e.g., page 21, lines 27-28, of the specification). Furthermore, Applicant has stated in the specification, that IL-1z is likely to have IL-12 promoting activities similar to IL-1g, in particular tumor activity (see, e.g., page 69, line 33 through page 70, line 2).

In support of this asserted utility, Applicant submits Gao, et al. (2003) J. Immunol. 170:107-113 ("Gao"). The Gao references teaches that IL-1H4/IL-1F7 (a.k.a. IL-1z) adenoviral mediated gene transfer of IL-1H4 to induce an IL-12- and Fas ligand dependent anti-tumor response. Gao further teaches that administration of this IL-1z adenoviral construct to mice lacking the IL-12p40 subunit of IL-12, failed to confer any anti-tumor activity. Thus the authors conclude that ". . . IL-1H4 may promote the development of the anti-tumor response through enhanced IL-12 production" (see, Gao, et al., supra, page 110, column 2).

It is well known that, in addition to anti-tumor activity, that IL-12 can enhance inflammation (see, e.g., Storkus, et al. in Thompson (ed) (1998) The Cytokine Handbook, 3rd ed., Academic Press, New York, NY, pp 391-425 ("Storkus")). Storkus teaches that inhibition of the proinflammatory cytokine, IL-12, would be beneficial in the treatment inflammatory conditions, e.g., transplantation, autoimmunity, arthritis, etc. (see, Storkus, supra, pp. 410-413). The present specification discloses that IL-1z, similar to IL-1g should ". . . have related activities . . . typically affecting similar immune functions, including inflammatory responses." (see, e.g., page 21, lines 4-8, of the specification). Applicant submits that the skilled artisan, knowing the proinflammatory action of IL-12, and that IL-1z synergizes and enhances IL-12 activities, would reasonably believe that the antibodies of the present invention should be useful in blocking, agonizing, or detecting IL-12 mediated inflammation. Thus, the present invention is supported by a substantial, specific, and credible utility.

For the Examiner's convenience, the above cited references and a GenBank printout of the sequence of IL-1H4 are provided along with a supplemental IDS. With regard to the 35 U.S.C. 112, first paragraph rejection, Applicant submits that because the present invention is, in fact, supported by a substantial, specific, and credible utility.

Thus, the skilled artisan would know how to make and use the antibodies of the present invention.

In view of the forgoing, Applicant submits that the rejection of Claims 21-27 under 35 U.S.C. §101 and §112, first paragraph, is overcome, and new Claim 34 is free from this rejection. Withdrawal of this rejection is respectfully requested.

IV. Rejections of Claims 22-27 under 35 U.S.C. 112, Second Paragraph.

The Examiner rejected Claims 22-27 under 35 U.S.C. §112, second paragraph. Claim 26 is canceled and the rejection is therefore moot as to this claim. In particular, The Examiner alleges finds Claim 22 as vague and indefinite, for reciting "glycosylated". Applicant respectfully disagrees with the Examiner. It is well understood by the skilled artisan that antibodies, when recombinantly expressed in mammalian and certain unicellular eukaryotic cells, as opposed to most bacterial hosts, possess various glycosylation patterns. When an antibody is glycosylated, it will possess glycosylation patterns characteristic of the host cell. Glycosylation and glycosylated are discussed in the specification, e.g., on page 46, lines 16-27, of the specification, as well as in various references cited throughout the application. For these reasons, Applicant believes that claim 22 is clear and definite.

The Examiner further found that claim 23 was vague and indefinite for reciting "including". Applicant has amended this claim to remove the word "including". Claim 34 is added to further define "aqueous compound". Applicant submits that Claim 23, as amended, and new Claim 34, are therefore clear and definite.

Claim 24 was rejected under this section for the recitation of "or a source of the polypeptide of SEQ ID NOs: 2 or 4". As amended, Claim 24 no longer recites this phrase, and is therefore clear and definite.

The Examiner rejected Claim 25 for lack of antecedent basis for the recitation of "the polypeptide of SEQ ID NO: 2 or 4". Applicant has amended this claim to state "a polypeptide of SEQ ID NO: 2 or 4, therefore, amended Claim 25 is now clear and definite.

Claim 27 was rejected under this section for reciting "polypeptide of SEQ ID NOs:2 or 4". As amended, Claim 27 now recites, "a polypeptide having the amino acid sequence of SEQ ID NOs: 2 or 4". Amended Claim 27 is now clear and definite.

In view of the forgoing, Applicant believes that the rejection of Claims 22-27 under 35 U.S.C. §112, second paragraph, is overcome, and new Claim 34 is free from this rejection. Withdrawal of this rejection is respectfully requested.

V. Rejection of Claims 21, 22, and 25-27 under 35 U.S.C. 102(e)

The Examiner rejected Claims 21, 22, and 25-27 under 35 U.S.C. 102(e) as being anticipated by US 6,117,654 ('654). Claim 26 is canceled and the rejection is therefore moot as to this claim. The '654 patent teaches a nucleic acids, polypeptides, and antibodies of TANGO-77. The Examiner asserts that because TANGO-77 has identity with SEQ ID NO: 2 or 4, then antibodies that bind to TANGO-77 will also bind to the polypeptides of present invention. With regard to Claims 21, 22, 25, and 27, Applicant respectfully disagrees with the Examiner's assertion.

Since the claimed antibodies or antigen-binding fragments specifically bind a polypeptide consisting of SEQ ID NO:2 or 4, they would not bind the TANGO-77 protein, which is different and unrelated from the polypeptide consisting of SEQ ID NO:2 or 4. The present specification teaches how to assay for specifically binding antibodies on page 62, line 12 through page 64, line 9, of the specification. A person of ordinary skill in the antibody art would not consider the antibody that binds both SEQ ID NO: 2 or 4 and TANGO-77 as specifically binding a polypeptide of SEQ ID NO:2 or 4. Therefore, '654 does not disclose the claimed antibodies, and thus fails to anticipate these antibodies.

Furthermore, this rejection is essentially an inherency rejection. To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference. Inherency, however, may not be established by probabilities or possibilities. *In re Robertson*, 49 USPQ2d 1949, 1950-1951 (Fed. Cir. 1999). MPEP §2112. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). MPEP §2112. In addition, the Examiner has the burden of proof. In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent

characteristic necessarily flows from the teachings of the applied prior art. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). MPEP §2112.

Applicant submits Tribbick, G. (2002) J. Immunol. Meth. 267:27-35 and Arnon and Van Regenmortel (1992) FASEB J. 6:3265-3274. Both references that epitopes bound by antibodies are generally discontinuous Consequently, the 50 amino acid sequence of '654, may not necessary be bound by an antibody that binds to SEQ ID NO: 2 or 4. Both references are provided with the above Supplemental Information Disclosure Statement.

Applicant submits that the '654 fails to anticipate the antibodies of the present invention. In view of the forgoing, Applicant believes that the rejection of Claims 21, 22, and 25-27 under 35 U.S.C. 102(e) is overcome, and may be properly withdrawn.

VI. Rejection of Claim 24 under 35 U.S.C. 103(a)

The Examiner rejected Claim 24 under 35 U.S.C. 103(a) as being unpatentable over '654 in view of the Stratagene catalog (1998, page 39). As noted above, the '654 patent fails to anticipate the antibodies of the present invention. The Stratagene catalog teaches combining reagents to form a kit. This reference fails to cure the deficiencies of the '654 patent. Thus, the present invention is patentable over the cited references.

In view of the above, the rejection of Claim 24 under 35 U.S.C. 103(a) is overcome. Withdrawal of this rejection is respectfully requested.

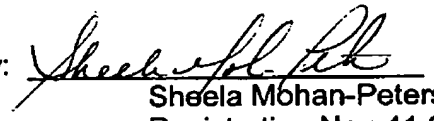
Conclusion

Applicant's current response is believed to be a complete reply to all the outstanding issues of the latest Office action. Further, the present response is a bona fide effort to place the application in condition for allowance or in better form for appeal. Accordingly, Applicant respectfully requests reconsideration and passage of the amended claims to allowance at the earliest possible convenience.

Applicant believes that no additional fees are due with this communication. Should this not be the case, the Commissioner is hereby authorized to debit any charges or refund any overpayments to DNAX Deposit Account No. 04-1239.

If the Examiner believes that a telephonic conference would aid the prosecution of this case in any way, please call the undersigned.

Respectfully submitted,

Date: January 27, 2006 By: 

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